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DETAILED ACTION

Acknowledgement is made of Applicant's remarks and amendments filed February 10, 2010. Acknowledgement is made of amendment to Claims 1, 17 and 18 and the addition of new Claim 38. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1, 3 – 25 and 33 – 38 are currently pending

Priority

This application, 10/533,063, filed 05/12/2006 is a national stage entry of PCT/GB03/04653, International Filing Date: 10/29/2003. This application claims foreign priority under U.S.C. § 119 of United Kingdom patent application GB0225197.3, filed 10/30/2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 11, 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

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Maintained Rejections

Claim rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 – 13, 15 – 16 and 36 <u>remain</u> rejected under 35 U.S.C. 102(b) as being anticipated by Short *et al.* in WO 01/31339 A1 (published: May 03, 2001) as evidenced by Alberts *et al.* in Molecular Biology of the Cell, Garland Publishing, 1983.

The Short reference teaches a method comprising providing an organic monomer, creating a plasma of said organic monomer and coating the surface with said plasma to provide a an assay surface (Claim 27). The reference further teaches performing a biological assay comprising providing a biological molecule bound to a substrate which has the characteristics of a surface which has been treated by plasma polymerization (page 9, lines 23 – 26). Short also teaches binding of immunoglobulin G (IgG) (an antibody) to plasma surfaces (page 12, 1st paragraph). The Alberts reference

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is provided as an evidentiary reference to illustrate that antibodies contain carbohydrate chains (page 965, Figure 17-17).

Regarding instant Claim 1, it is the position of the Examiner that Short teaches the steps, as part of said biological assay, in which a biological molecule is bound to a surface which has been treated by plasma polymerization. The step of 'binding' is reasonably interpreted as the biological molecule contacting the plasma treated surface. It is further the position of the Examiner, absent a showing of evidence to the contrary. that the newly added limitation of passively absorbed on the surface "and thereby immobilized" recited in instant Claim 1, step v, is met by the disclosure of Short that the biological molecule is 'bound' to the plasma treated surface (page 9, lines 23 – 26). Regarding the newly added limitation to instant Claim 1 of "incubating said plasma polymer coated surface with said carbohydrate", the Short reference teaches an Example wherein the IgG antibody (referred to by Short as a 'protein') was allowed to bind to the (plasma copolymer) surfaces overnight (page 12, 1st paragraph), which is clearly an incubation step. Finally, the limitation in instant Claim 1, step v, that the passively absorbed and thereby immobilized carbohydrate molecule retains it's biological activity, is accorded no patentable weight as such an outcome would necessarily result from the method steps taught by Short which, as noted above, are the same as those recited in the instant Claim.

Regarding instant Claim 3, the Short reference teaches an Example of an immunoassay in which the antibody (carbohydrate) is in solution (page 13, lines 2 – 12).

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Instant Claims 4-7 and 11 are drawn to the composition of the monomer in the method of instant Claim 1. Regarding instant Claims 4-7, the Short reference teaches plasma monomers that are volatile alcohols, amines, hydrocarbons and acids (page 3, lines 27-31 and Claim 22). Regarding instant Claim 11, the volatile alcohols, amines and acids taught in the rejection of instant Claims 4, 5 and 7, contain hydroxyl, amino and carboxylic acid groups, respectively (see also page 8, lines 1-4, specifically teaching, allyl alcohol, acrylic acid and allyl amine).

Regarding instant Claims 8 – 10, drawn to the percent nitrogen content on surface comprising a polymer, formed by the method of instant Claim 1 Short teaches the allyl amine-based polymer surface prepared by the method of instant Claim 1, has a nitrogen content greater than 20% (page 14.5 – 9).

Regarding instant Claim 12, the reference teaches that the monomer comprising the method of instant Claim 1 is allylamine (page 14, 5 – 9).

Instant Claim 13 is drawn to the vapor pressure of the monomer. The Short reference teaches the same monomers as the instant application, accordingly, the monomers would necessarily have the same vapor pressure properties.

Regarding instant Claims 15, 16, 35 and 36, the Short reference teaches the limitation of a polymer composition comprising an amine copolymer obtained by plasma polymerization of alkanes and alkenes (page 8, lines 6 – 7 and 20 – 26, Claims 22 – 25; instant Claims 15, 16 and 36).

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Claims 1, 3, 5 – 7, 11, 18 – 20 and 22 <u>remain</u> rejected and Claim 38 is rejected under 35 U.S.C. 102(b) as being as being anticipated by Yan et al. in US patent 6,776,792 (filed: April 24, 1997).

This rejection is maintained but is modified by the addition of new Claim 38.

Yan et al. teach an implantable stent coated with a material that attracts the glycosaminoglycan carbohydrate heparin (instant Claims 18 - 20 and 38) and forms a bond (i.e. heparin contacts a surface and is immobilized; Abstract). Yan teaches that the stent surface coating is formed by plasma deposition with methane, ammonia gas, other amine containing monomers and acrylic acid (page 3, lines 6 - 22; instant Claim 1, steps i – iii and Claims 5 – 7 and 11). Yan also teaches contacting the plasma coated surface (instant Claim 1, step iv) with heparin, via ionic bonds (Figure 2 and column 2, lines 1 - 5 teach an ionic bonding interaction between heparin and the surface; instant Claim 1, steps i - iv). Finally, Yan teaches the incubation step recited in amended Claim 1 (step v) by pretreating the plasma coated surface (stent) with a heparinized saline solution (instant Claim 3) prior to implantation in order to adjust the heparin level (column 4, lines 4-7). Therefore, the carbohydrate is immobilized using the method steps recited in instant Claim 1 and accordingly, such an outcome results in heparin being passively (ionically) absorbed and retaining is anticoagulant biological activity (column 1, lines 8 - 24).

Claim 22 is drawn to the method of instant Claim 1 wherein the surface is part of a therapeutic vehicle. This limitation is taught by Yan in which a carbohydrate, heparin, is immobilized on the surface of a stent (a therapeutic vehicle).

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Claim rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 33 – 34 <u>remain</u> rejected under 35 U.S.C. 103(a) as being unpatentable over Short et al. in WO 01/31339 A1 (published: May 03, 2001) as evidenced by as evidenced by Alberts et al. in Molecular Biology of the Cell, Garland Publishing, 1983 as applied to 1, 3 – 13, 15 – 16 and 36 in the 102(e) rejection above, as evidenced by Karwoski et al. in US patent 6,632,842 (published December 30, 1986).

Short, as evidenced by Alberts, teaches the limitations of instant Claims 1, 3, 5 – 7. 11. 18 – 20 and 22. Regarding instant Claims 14. 33 and 34 drawn to the plasma

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power input ratio W/FM, Short teaches the conditions for plasma polymerization in which the plasma power is < 10 W (page 9, lines 17 - 18), the monomer flow rate < 5cc/min (page 9, lines 17 – 18), a reactor pressure of approximately 1.5 x 10⁻¹ mbar. (page 11, lines 7 – 9) and RF power of 13.56 MHz (page 10, line 26). When these parameters for plasma polymerization are read in light of those recited on page 15 of the instant specification (W<10, flow rate between 1 – 5 cc/min, pressure 'around 2 x 10⁻¹ ² mbar' and RF power of 13.56 MHz) it appears that the plasma power of Short is deposited from a plasma (W/FM) within the same ranges as those claimed in instant Claims 14, 33 and 34. The Karwoski reference is cited to provide evidence that the formula W/FM represents the type of gas used, the gas flow rate and pressure, and the RF field strength, wherein W denotes discharge power (which is proportional to field strength). F is the flow rate of the gas, and M is the molecular weight of the plasma gas (column 10, lines 27 – 31). Thus, one would have been motivated to use the ranges for W/FM recited in instant Claims 14, 33 and 34 because these same ranges have already been successfully used by Short to provide plasma coated assay binding surfaces containing the same genus of plasma monomers.

Claim 17 <u>remains</u> rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. in US patent 6,776,792 (filed: April 24, 1997), as applied to Claims 1, 3, 5 – 7, 11, 18 – 20, 22 and 38 in the 102(e) rejection above, and further in view of Mori et al. in US patent 5,053,398 (published: October 1, 1991).

This rejection is maintained but is modified by the addition of new Claim 38.

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Yan teaches the limitations of instant Claims 1, 3, 5-7, 11, 18-20, 22 and 38 but does not teach the method of instant Claim 1 wherein the carbohydrate is a homopolysaccharide.

Regarding instant Claim 17, Mori discloses sulfated homopolysaccharides with anti-HIV activity (Title). One of ordinary skill, cognizant of the teachings of Yan regarding immobilization of the polyanionic carbohydrate heparin on a plasma treated surface to gain benefit of it's anticoagulant activity when administered to a patient, would have been motivated to adapt the method of Yan to immobilize the polyanionic carbohydrate of Mori to a plasma coated surface in order to obtain the benefit of it's anti-HIV activity when administered to a patient. Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to adapt the method taught by Yan, to immobilize the homopolysaccharide of Mori to a surface, with a reasonable expectation of success, in order to obtain the benefit of delivering the anti-HIV homopolysaccharide drug to a patient in need.

Claim 35 <u>remains</u> rejected under 35 U.S.C. 103(a) as being unpatentable over Short et al. in WO 01/31339 A1 (published: May 03, 2001) as evidenced by Alberts et al. in Molecular Biology of the Cell (Garland Publishing, 1983), as applied to Claims 1, 3 – 13, 15 – 16, 18 – 20, 22 and 36 in the 102(b) rejection above, in view of Nomura in US patent 6,022,602 (published: February 8, 2000).

Short teaches the limitations of instant Claims 1, 3 – 13, 15 – 16, 18 – 20, 22 and 36. Short teaches that the plasma comprises an amine copolymer comprising a

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hydrocarbon such as an alkene, alkyne or diene but is silent on the limitation that the hydrocarbon is an alkane (instant Claim 35).

Nomura teaches plasma modification of lumen surface tubing (Title, said tubing having usefulness in medical devices (Abstract). Nomura teaches that polymerizable monomers include allylamine, alkanes and alkenes etc. and may comprise a mixture of said monomers (column 13, lines 9 – 17). Accordingly, the skilled artisan, cognizant that the monomers taught by Nomura for the plasma gas sources, can be selected from alkanes (instant Claim 35), olefins, allylamine, acrylic acid etc. and mixtures thereof, would have been motivated to employ these monomer mixtures in order to, through routine experimentation, optimize the coating properties.

Claim 21 <u>remains</u> rejected under 35 U.S.C. 103(a) as being unpatentable over Short et al. in WO 01/31339 A1 (published: May 03, 2001) as applied to Claims 1, 3 – 13, 15 – 16 and 36 above, and further in view of Nilsson et al. in US2001/0017270 (published: August 30, 2001).

As noted above, Short teaches the limitations of instant Claims 1, 3 - 13, 15 - 16 and 36, drawn to a surface to which biological molecules may bind and be assayed but do not teach the limitations of instant Claim 21 in which the surface of instant Claim 1 is part of a biosensor.

Instant Claim 21 is drawn to the surface of instant Claim 1, wherein the surface is part of a biosensor. Nilsson teaches immobilized carbohydrate biosensors in which the carbohydrate or derivative is used to generate a detectable signal via specific binding of a protein, virus or cell (Abstract, section [0001]. One would have been motivated to

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adapt the method of Short, wherein the surface is part of a biosensor, because both the assay surface of Short and that of Nilsson teach the binding of biological molecules to a surface. Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to adapt the method taught by Short in which biological molecules bind and are assayed, to a biosensor surface, in which macromolecules also bind and are assayed, in order to gain the benefit of generating a detectable signal in response to protein virus or cell binding.

Claim 23 <u>remains</u> rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. in US patent 6,776,792 (filed: April 24, 1997), as applied to Claims 1, 3, 5 – 7, 11, 18 – 20 and 22 in the 102(e) rejection above, and further in view of Earhart et al. in US patent 6,077,232 (published June 20, 2000).

As noted above in the 102(e) rejection above, Yan teaches the limitations of instant Claims 1, 3, 5 – 7, 11, 18 – 20 and 22, drawn to a surface of a stent which serves as a substrate for the delivery of the anticoagulant heparin, but does not teach the limitations of instant Claim 23 in which the surface of instant Claim 1 is part of a biological sample collection device.

Earhart teaches a blood (biological sample) collection device comprising the carbohydrate heparin to inhibit the coagulation of blood samples (Abstract and Figures 1 and 2). Earhart is silent on the source of the blood as recited in instant Claims 23 and 37 (animal and human respectively) disclosing that the blood is that of a 'donor' (column 5, Chart A). One would have been motivated to adapt the stent surface of Yan, which delivers the anticoagulant heparin to the blood of a patient upon implantation, to a

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surface that is part of a blood collection device (Earhart) since both references teach the use of the carbohydrate heparin for the same purpose, to inhibit the coagulation of blood.

Claim 24 <u>remains</u> rejected under 35 U.S.C. 103(a) as being unpatentable over Short et al. in WO 01/31339 A1 (published: May 03, 2001) as applied to Claims 1, 3 – 13, 15 – 16 and 36 above, and further in view of Brigstock et al. in US 20010007019 (published: July 5, 2001).

As noted in the 102(b) rejection above, Short teaches the limitations of instant Claims 1, 3 - 13, 15 - 16 and 36, drawn to a surface to which biological molecules bind and are assayed, but the reference does not teach the limitations of instant Claim 24 in which the surface of instant Claim 1 is part of an affinity purification matrix.

Brigstock teaches heparin binding to identify heparin growth factor (HBGF) polypeptides as part of an affinity purification matrix and, in a specific Example, applies the method to purify uterine luminal flushings (paragraphs [0017] and [0018]; Figures 1a and 1b). Brigstock teaches that HBGF polypeptides each have different heparin binding properties (paragraph [0027]). One would have been motivated to adapt the surface of Short as part of an affinity purification matrix for the detection and purification of HBGF, as taught by Brigstock because both surfaces teaches binding of carbohydrates and would therefore be able to detect and purify HGBF in order to gain benefit of therapies related to uncontrolled tissue growth (paragraph [0030]).

Claim 25 <u>remains</u> rejected under 35 U.S.C. 103(a) as being unpatentable over Short et al. in WO 01/31339 A1 (published: May 03, 2001) as applied to

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Claims 1, 3 – 13, 15 – 16 and 36 above, and further in view of Dukler *et al.* in US2002/0094541 (published: July 18, 2002).

As noted in the 102(b) rejection above, Short teaches the limitations of instant Claims 1, 3 - 13, 15 - 16 and 36, drawn to a surface to which biological molecules bind and are assayed, but the reference does not teach the limitations of instant Claim 25 in which the surface of instant Claim 1 is part of a microarray.

Dukler teaches a method of identifying a carbohydrate capable of binding to other entities such as polypeptides via a library of carbohydrate structures attached to a surface at a specific and addressable location of an array (Abstract, Claim 1). Dukler teaches that carbohydrate libraries, attached to a solid support (a surface) can be used to identify carbohydrate associated receptors as potential targets for drug therapy (paragraph [0002]). Accordingly, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to adapt the surface carbohydrate immobilization method disclosed by Short wherein the surface is part of a microarray in order to identify potential new targets for drug therapy, as taught by Dukler.

Response to Arguments

Applicant's arguments amendments filed February 1, 2010 with respect to the rejections cited above under 35 U.S.C 102(b) and 35 U.S.C 103(a) of Claims 1, 3 – 25 and 33 – 38 have been fully considered but are not found to be persuasive. Applicant has amended the method of Claim 1 to require in step (iv) that the biologically active carbohydrate molecule be "in it's native form" and that "the plasma polymer coated

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surface is not modified prior to contacting with said carbohydrate molecule in its native form". Applicant has amended step (v) to require that the carbohydrate molecule be "in its native form" when it is passively adsorbed on the surface and thereby immobilized, such that the carbohydrate molecule, "remain in its native form".

Applicant argues that amended Claim 1 overcomes the applied 102(b) rejection over Short et al. and thereby renders Claims 1, 3 – 13, 15 – 16, 36 and 38 patentable. Applicant cites p [0055] of the present specification which discusses the challenges of preparing surfaces for assays to promote the passive adsorption of negatively charged surfaces. Applicant cites p [0056] of the present specification to emphasize that, "in assays, it is preferred that the polysaccharide is adsorbed pure and not be contaminated (e.g. with albumin or salts) or that the surface is first modified by the binding of a first biomolecule, for example, albumin) that will in turn bind the polysaccharide" (Remarks, page 7). These arguments are not found to be persuasive because, the antibody of Short, human immunoglobulin G (IgG), appears, absent any specific evidence to the contrary to contact directly the plasma polymer coated surface without prior modification of the coated surface (page 12, Short, Enzyme Immunoassay section, 1st paragraph), as recited in Claim 1. Further, the antibody of Short appears to be in its "native form", as recited in Claim 1, which, based on p [0020] of the present specification "includes carbohydrates which are not physically or chemically modified".

Applicant argues that the Yan reference teaches "bonding" of heparin to the plasma modified surface of a stent and not "immobilization" as required in instant Claim 1 (Remarks, page 8, final paragraph to page 9, 1st paragraph). Applicant argues that

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Yan teaches that "a heparin molecule may become detached" and that "the heparin may need to be replenished" (following implantation). Applicant cites p [0051] of the present specification which states that passive adsorption (binding) of a carbohydrate to a surface "should be sufficiently strong that the polysaccharide is immobilized to the extent that it cannot be desorbed by washing". This argument is not found to be persuasive because the specification does not provide a limiting definition of immobilization. Accordingly, one of ordinary skill would reasonable interpret the limitation of "immobilized" to include varying degrees of binding to a surface. Thus, as noted in the maintained 102(b) rejection, one of ordinary skill would consider the binding of negatively charged heparin to the positively charged surface of the plasma treated stent to fall within the scope of immobilization. Further, Yan teaches that a physician may pre-treat the plasma modified stent by first flushing it with a heparinized saline solution before implantation in order to adjust the heparin level. Clearly, the heparin bound to the stent of Yan is immobilized (i.e. not desorbed by washing) prior to implantation.

Regarding the rejection of Claim 22 (Short in view of Nilsson), Applicant argues that the Nilsson reference fails to teach or suggest a plasma polymerized surface or utilize a carbohydrate in its native form and therefore does not overcome the alleged deficiencies of Short. Arguments rebutting Applicant's arguments regarding the Short reference have been addressed above. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re*

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Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant, has argued the deficiencies of the Nilsson reference alone, however, the rejection is based on the combination of Short and Nilsson.

Regarding the rejection of Claim 23 (Yan in view of Earhart), Applicant argues that the Earhart reference fails to teach immobilization of heparin as taught by Yan. Arguments rebutting Applicant's arguments regarding the Yan reference have been addressed above. In response to applicant's arguments against the Earhart reference, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant, has argued the deficiencies of the Earhart reference, however, the rejection is based on the combination of Short and Nilsson. The motivation cited above to modify the heparin based blood collection device of Nilsson with the heparinized stent surface of Yan was that each reference was directed to prevention of blood coagulation using heparin.

Regarding the rejection of Claim 24 (Short in view of Brigstock), Applicant argues that the Brigstock reference which teaches the use of a heparin immobilized affinity column to separate heparin binding polypeptides does not overcome the alleged deficiencies of Short (addressed above). In response to applicant's arguments against the Brigstock reference, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re*

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Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As noted in the 103(a) rejection above, one would have been motivated to modify the surface of Short with the immobilized heparin of Brigstock in order to detect and purify HGBF and gain benefit of therapies related to uncontrolled tissue growth.

Regarding the rejection of Claim 25 (Short in view of Dukler), Applicant argues that because Dukler teaches a preference for covalent binding of a carbohydrate to the solid phase support one of ordinary skill would not have been motivated to modify the surface of Short as part of a microarray. In response to applicant's arguments against the Dukler in combination with Short it is acknowledged that Dukler teaches a preference for covalent attachment. However, the plasma modified surfaces of Short show selective increased affinity for biological molecules. Accordingly, because the surfaces of Short and Dukler are similarly directed toward high affinity binding (immobilization) of carbohydrates one of ordinary skill would have been motivated to modify the surface of Short as part of a microarray in order to identify potential new carbohydrate associated receptor targets for drug therapy.

Conclusion

Claims 1, 3 – 25 and 33 – 38 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PADMANABHAN SREENIVASAN can be reached at (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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DH /Brandon J Fetterolf/ Primary Examiner, Art Unit 1642